

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 16 NOV 2004

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Applicant's or agent's file reference 12272440/EJH/JTC	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU2003/000903	International Filing Date (day/month/year) 11 July 2003	Priority Date (day/month/year) 11 July 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A01H 5/00		
Applicant BUREAU OF SUGAR EXPERIMENT STATIONS et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 18 December 2003	Date of completion of the report 27 October 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer CHRISTOPHER LUTON Telephone No. (02) 6283 2256

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU2003/000903

I. Basis of the report

1. With regard to the elements of the international application:*

- ☐ the international application as originally filed.
- ☒ the description, pages 1-125, as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 126-129, received on 23 September 2004 with the letter of 22 September 2004
- ☒ the drawings, pages 1-16 , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☒ the sequence listing part of the description:
pages 1-70 , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☒ the claims, Nos. 13-54
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/AU2003/000903

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-12	YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims 1-12	NO
Industrial applicability (IA)	Claims 1-12	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1 US 6 091 002 A (Asrar *et al*)
- D2 WO 00/52183 A1 (Monsanto Company)
- D3 WO 01/23596 A2 (Pioneer Hi-Bred International, Inc)
- D4 Snell KD *et al*, *Metabolic Engineering*, January 2002, 4(1):29-40
- D5 Hahn JJ *et al*, *Biotechnology Progress*, 1999, 15:1053-1057
- D6 Brumbley SM *et al*, *Proceedings of the Conference of the Australian Society of Sugar Cane Technologists*, 29 April to 1 May 2002, 24:40-46
- D7 Bohmert K *et al*, *Planta*, 2000, 211:941-945

NOVELTY (N) and INVENTIVE STEP (IS) Claims 1-12

D1-D3 describe the modification of polyhydroxyalkanoate biosynthesis in plants. D1-D3 disclose and suggest modification of the same pathways and enzymes as disclosed by the present application. D1-D3 suggest sugarcane as a plant in which PHAs may be produced. In response to the first International Preliminary Examination Opinion, the Applicant asserted that none of D1-D3 exemplify the production of PHAs in sugarcane. Therefore, claims 1-4 and 7-11 are novel in light of D1-D3.

However, in light of the fact that D1-D3 suggest sugarcane as a species in which PHAs may be produced, and the fact that there would not appear to have been a problem to overcome in doing so, the claims do not involve an inventive step in light of D1-D3. The response to the first International Preliminary Examination Report suggested that few laboratories in the world actually produce transgenic sugarcane. This is not considered evidence of a technical problem requiring the exercise of inventive faculty to overcome.

The responses to the first and second International Preliminary Examination Reports suggested that the present claims are inventive on the basis that the use of sugarcane represents an inventive selection of one plant from among many. The response to the second International Preliminary Examination Opinion cited certain legal doctrine relating to the criteria for a valid "selection patent". However, the cited doctrine relates to the issue of novelty and is not considered relevant to the question of inventive step. As noted, D1-D3 expressly suggest sugarcane as a plant in which PHAs may be produced.

D4 and D5 describe the modification of polyhydroxyalkanoate biosynthesis in plants but do not suggest modification of sugarcane. Therefore, the claims are novel and involve an inventive step in light of D4 and D5.

(continued...)

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V

D6 describes the modification of polyhydroxyalkanoate biosynthesis in sugarcane (see abstract). D6 indicates that this was achieved by the use of the biolistic method (abstract). D6 describes the benefits and advantages of altering polyhydroxyalkanoate biosynthesis in sugarcane. The claims are not considered to involve an inventive step in light of D6 when read in light of any one of D1-D3. D1-D3 describe methods and constructs that could be used to achieve the methods and plants of D6.

The response to the second International Preliminary Examination Report suggested that D6 does not constitute an enabling disclosure. However, D6 in combination with any one of D1-D3 is considered to sufficient instruction to the person skilled in the art to perform the invention. D6 discloses biolistic methods for transformation. D1-D3 describe methods and constructs that could be utilised in such methods.

The response to the first International Preliminary Examination Report suggested that none of D1-D3 "provides any direction as to how to successfully produce a PHA-producing sugarcane plant, nor do they provide any motivation for a person skilled in the art to attempt to produce transgenic sugarcane". However, as noted in at least D1:

"Transformation of a wide variety of different monocots and dicots by particle gun bombardment is routine in the art (Hinchee et al., 1994; Walden and Wingender, 1995)" (column 109, line 41).

It is notable that this is the same method employed by the present Applicant.

Industrial Applicability (IA) Claims 1-12

The claims are considered to have industrially applicability.